FDA 510(k) Premarket Notification

K954413 KELOCOTE

CLEARED

Nov 29, 1995
69 days to decision

K954413 · Product code: **MDA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k954413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Sep 21, 1995
Decision date	Nov 29, 1995
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Allied Biomedical Corp.**
Location	Paso Robles, CA, US
Contact	CATHY RIPPLE
510(k) history	9 submissions · 9 cleared · 1995-1998